



TITLE:

Transurethral resection of benign prostatic hyperplasia using a vaporizing resecting loop, UROloop

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TRANSURETHRAL RESECTION OF BENIGN PROSTATIC HYPERPLASIA USING A VAPORIZING RESECTING LOOP, UROLOOPTM

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New electrosurgical instruments for the treatment of benign prostatic hyperplasia (BPH) have been developed during the past few years. We determined the efficacy and safety of transurethral prostatectomy (TUR-P) using a new electrosurgical device (UROloopTM) for the treatment of BPH.

Twenty-four patients, with a mean age of 67.7 years, with BPH underwent TUR-P using the UROloop between April 1996 and March 1997. We evaluated the pre- and postoperative symptom scores and urodynamic parameters of the patients. The International Prostate Symptom Score (IPSS) was used for symptom scoring. The urodynamic parameters included peakflow rates (PFR) and postvoid residual urine (PVR).

The average preoperative IPSS score for all patients was 15.4 ± 1.4 . The IPSS score was significantly improved to 4.3 ± 0.24 at 12 weeks after the TUR-P ($p=0.0002$). The average PFR was increased by 117% at 12 weeks postoperatively. The average preoperative PVR of 65.4 ml was reduced to 15.2 ml postoperatively. The changes in the urodynamic parameters were statistically significant. No severe complications were observed in the present study. The changes in the serum sodium and hemoglobin levels were small.

This study revealed significantly sustained clinical improvement with minimal morbidity. The results of the present study also confirmed the usefulness of the new endoscopic treatment for BPH.

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Key words: TUR-P, Vaporizing resecting loop, Benign prostatic hyperplasia

INTRODUCTION

Benign prostatic hyperplasia (BPH) is the most common cause of abnormal voiding symptoms in men age 40 years or older, resulting in clinically significant symptoms in 10 to 20% of men in this age group. Transurethral prostatectomy (TUR-P) is well established as the gold standard for the treatment of BPH. However, this technique still causes some morbidity which includes bleeding, transurethral resection syndrome, retrograde ejaculation, and incontinence. In this respect, many new techniques for the treatment of BPH have been developed as an alternative to TUR-P during the last few years. We have performed TUR-P assisted by the new electrosurgical device UROloopTM which was introduced very recently, and determined the efficacy and safety of this modality.

MATERIALS AND METHODS

Patients

A total of 24 patients with moderate to severe symptoms of prostatism underwent TUR-P assisted by the UROloopTM between April 1996 and March 1997 at Tsukuba Gakuen Hospital. Informed consent was obtained in all cases. The patients

fulfilled the minimal criteria for entry which was an International Prostate Symptom Score (IPSS) of 10 or higher, and a peak flow rate of less than 15 ml/sec. Six of the patients were in urinary retention. Patients with a neurogenic bladder or prostate cancer were excluded.

The diagnostic workup included a history and physical examination, laboratory evaluation (urinalysis, urine culture, serum electrolytes, complete blood count and prostatic specific antigen), uroflow using a Duntec Urodyne 5,000 machine, and performing transrectal ultrasound measurement of the prostate size.

The patients had a mean age of 67.7 years (range: 57-78), and their assumed prostatic volume was 52.6 ± 6.5 g (range: 15.0-144.8). The average preoperative IPSS was 15.4 ± 1.4 , PFR 12.1 ± 0.8 ml/sec and PVR 65.4 ± 21.1 ml.

The patients were assessed at baseline for both safety and efficacy and followed-up at 1 week and 12 weeks. The parameters of evaluation were divided into two categories: (1) efficacy: IPSS, PFR and PVR; (2) safety: incidence of side effects, changes in serum sodium and hematocrit values. To determine the safety of UROloop resection, we compared the degree of hemoglobin and serum sodium change with

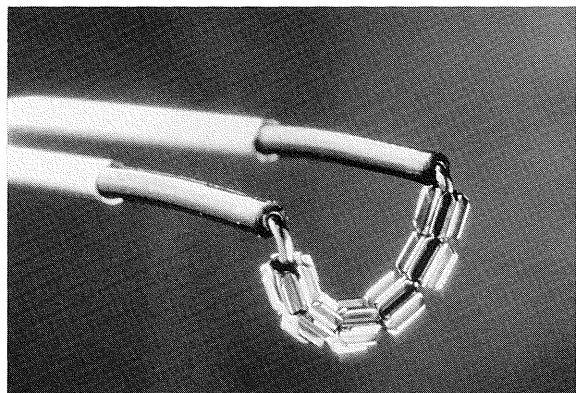


Fig. 1. The UROloop™ electrode. Its surface design is a combination of rolling elements with individual grooved areas.

a historical control group which consisted of 11 patients with BPH who underwent the standard TUR-P between April 1995 and March 1996 at Tsukuba Gakuen Hospital. The patients had a mean age of 70.0 years (range: 63–78), and their assumed prostatic volume was 22.1 ± 2.5 g (range: 15.0–38.0).

Equipment

Standard transurethral resection equipment was utilized, which included a continuous flow Richard Wolf 26F and a Circon ACMI 25.6 F resectoscope with a ERBOTOM ICC 350 electrical current generator. The UROloop™ is a specially designed resectoscope loop developed by ENDOcare Inc. that fits standard resectoscope equipment in place of a standard TUR loop. Its surface design is a combination of rolling elements with individual grooved areas. The resulting tissue response is a simultaneous cutting and vaporization effect (Fig. 1). Resection with the UROloop was generally accomplished at a cutting current that has about 20% higher power than a standard TUR-P. The average setting was 200 W for cutting and 80 W for coagulation.

Operative procedure

The operation was carried out by video endoscopy. Before the actual operation, a urethrocystoscopy was carried out. Mannitol-sorbitol was used for irrigation. The technique of Uroloop resection was the same as that of standard TUR-P. However, if a middle lobe was present, the operation began at that point. Tissue sampling was performed by changing to a standard TUR loop during the procedure.

Statistical analyses

The statistical analyses of this study were performed using the nonparametrics paired Wilcoxon signed rank test.

RESULTS

Urodynamic parameters

The post-operative results of subjective and

Table 1. Changes in efficacy parameters

	Baseline	1 week	12 weeks
IPSS	15.4 ± 1.4	4.3 ± 0.27	$4.3 \pm 0.24^*$
PFR (ml/s)	12.1 ± 0.8	23.2 ± 1.17	$26.2 \pm 1.85^{**}$
PVR (ml)	65.4 ± 21.1	11.3 ± 5.0	$15.2 \pm 7.8^{***}$

* $p=0.0002$, ** $p=0.0002$, *** $p=0.033$.

Table 2. Comparison with the standard TUR-P; degree of hemoglobin and serum sodium decrease

	UROloop™	Standard TUR-P
Hemoglobin (g/dL)	$1.43 \pm 0.26^*$	4.1 ± 0.82
Serum sodium (mEq/L)	2.34 ± 0.89	3.18 ± 1.89

* $p=0.003$.

objective parameters are shown in Table 1. Twelve weeks post-operatively, 72% improvement in the mean symptom score (15.4 ± 1.4 vs. 4.3 ± 0.24 , $p=0.0002^*$), 77% reduction in the mean PVR (65.4 ± 21.1 ml vs. 15.2 ± 7.8 ml, $p=0.033^*$) and 117% increase of PFR (12.1 ± 0.8 ml/s vs. 26.2 ± 1.85 ml/s, $p=0.0002^*$) were observed with a significant difference.

Changes in serum sodium and hemoglobin

There were no operative problems in any patients. None of the patients suffered any serious hemorrhage or TUR syndrome nor did they require any blood transfusion.

Serum sodium and hemoglobin levels were measured before, and 1, 24, and 72 hours after surgery. The lowest value was determined as the post-operative value. The mean difference in serum sodium and hemoglobin values was 2.34 mEq/l (from 141.67 mEq/l to 139.33 mEq/l) and 1.43 g/dl (from 14.50 g/dl to 13.07 g/dl), respectively.

Although the assumed prostatic volume of the patients who underwent TUR-P using the UROloop was significantly greater than that in the standard TUR-P group ($p=0.006^*$), the decrease in hemoglobin level in the UROloop group was significantly less ($p=0.003^*$). The decrease in the serum sodium level in the UROloop group was also less although the difference was not significant (Table 2).

Operative time

The mean operative time was 94.7 ± 3.2 minutes in the UROloop group and 76.6 ± 7.2 minutes in the standard TUR-P group. The UROloop-resection time was related to the size of the prostate, and 7 cases larger than 70 g, with an average operative time of 111.6 minutes, were included in the UROloop group.

DISCUSSION

The initial results of this study clearly showed significant improvements in both subjective and objective parameters; IPSS, PVR and PFR. On the other hand, the operating procedure was well

tolerated.

The UROloopTM, a vaporizing resecting loop made by ENDOcare Inc., is a new type of electro-surgical device developed from a grooved electrode for electrovaporization. We can remove prostatic tissue located on the device, and make a good coagulation zone from 1 to 3 mm deep at the underlying tissue, with no specially acquired skills other than those required for performing conventional TUR-P.

A prostatic defect cavity was formed at the end of the procedure similar to conventional TUR-P^{1,2)}, and gave a good short-term efficacy, with improved intra- and perioperative hemostasis as well as transurethral electrovaporization of the prostate (TVP)³⁻⁶⁾. Kaplan et al.^{3,4)} described the advantages of TVP as being the low intraoperative and perioperative morbidities, rapid convalescence time, short hospital stay, reduced equipment cost, and simplicity of procedure. On the other hand, Nishimura et al.⁷⁾ reported the following disadvantages of TVP; 1) there are too many bubbles which do not occur in conventional TUR-P, 2) the roller electrode disrupts the surgical view much more than a conventional TUR-P does, 3) coagulation of a bleeding site is more difficult than in TUR-P, 4) the depth of the prostatic tissue being treated is more difficult to determine, 5) pathological examination is not possible, and the estimation for vaporized tissue is difficult, 6) tags are difficult to remove especially at the distal end of the prostatic urethra, and 7) the surface of the surgical site appeared to be rougher than that after TUR-P.

UROloop was devised to allow more adequate vaporization and hemostatic resection. With the new electrode, we feel that there is good hemostatic effect as with TVP, without any conspicuous disturbance of the surgical view from its conventional resecting loop-like shape, and that removing tags, making a smooth surface and coagulating a bleeding site, is easier than with TVP. We thought these as an advantage of UROloop over TVP with roller type electrodes. Moreover, we believe that this technique could be especially useful in patients with bleeding dyscrasia and those taking anticoagulants. We also believe that this procedure, which does not limit the size of the prostate, would expand the indication of transurethral surgery for BPH.

Among the alternatives to TUR-P, the UROloop resection is mostly recommended for patients with advanced age and poor general condition as it

requires a short hospital stay and low invasiveness. Moreover, it does not require any excessive capital expenditure on new equipment such as laser generators and fibers aside from the UROloop electrode.

The follow-up is still rather short, but results after 12 weeks are promising. A longer follow-up with more patients, and randomized controlled trials comparing this new type of TUR-P with conventional TUR-P and laser ablation of the prostate are required.

CONCLUSION

In this study, we found significantly sustained clinical improvement with minimal morbidity. The results of the present study also confirm the usefulness of the new endoscopic treatment for BPH.

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和文抄録

電気蒸散切除電極 UROloopTM を用いた経尿道的前立腺切除術

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近年の前立腺内視鏡手術の進歩は著しいものがある。われわれは、米国 ENDOcare 社により開発された電気蒸散切除電極 UROloopTM を用いた TUR-P を行い、その治療効果と安全性について検討した。

対象は1996年4月より1997年3月までの間、筑波学園病院において UROloop を用いて TUR-P を施行した24症例である。おのおのの症例で IPSS, 最大尿流量 (PFR), 残尿量 (PVR) を治療効果指標として、また手術前後の血中ヘモグロビン値とナトリウム値も安全指標として比較検討した。

IPSS の平均値は術前値 15.4 ± 1.4 から術後12週で

4.3 ± 0.27 へ有意 ($p=0.0002$) に低下し、PFR も術前 12.1 ± 0.8 ml/s から術後 26.2 ± 1.85 ml/s へ ($p=0.002$)、PVR も術前 65.4 ± 21.1 ml から術後 15.2 ± 7.8 ml へ ($p=0.033$) とそれぞれに有意に改善した。一方で重篤な合併症は認められず、術前後の血清ナトリウムとヘモグロビン値の変化はわずかであった。

今後の長期観察も重要であると思われたが、今回の結果は本法の BPH 症例に対する優れた治療効果と安全性を示すものである。

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